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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
10/804,502	03/19/2004	Mary L. Cunningham	04289-00190-US	7682
23416 7590 01/11/2007 CONNOLLY BOVE LODGE & HUTZ, LLP P O BOX 2207 WILMINGTON, DE 19899			EXAMINER KHARE, DEVESH	
			ART UNIT	PAPER NUMBER
			1623	
SHORTENED STATUTORY PERIOD OF RESPONSE		MAIL DATE	DELIVERY MODE	
3 MONTHS		01/11/2007	PAPER	

**Please find below and/or attached an Office communication concerning this application or proceeding.**

If NO period for reply is specified above, the maximum statutory period will apply and will expire 6 MONTHS from the mailing date of this communication.

**Office Action Summary**

Application No.

10/804,502

Applicant(s)

CUNNINGHAM ET AL.

Examiner

Devesh Khare

Art Unit

1623

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

**Period for Reply**

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) OR THIRTY (30) DAYS, WHICHEVER IS LONGER, FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

**Status**

- 1) ☒ Responsive to communication(s) filed on 06 October 2006.
- 2a) ☒ This action is **FINAL**. 2b) ☐ This action is non-final.
- 3) ☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

**Disposition of Claims**

- 4) ☒ Claim(s) 1-19 is/are pending in the application.
- 4a) Of the above claim(s) \_\_\_\_\_ is/are withdrawn from consideration.
- 5) ☐ Claim(s) \_\_\_\_\_ is/are allowed.
- 6) ☒ Claim(s) 1-19 is/are rejected.
- 7) ☐ Claim(s) \_\_\_\_\_ is/are objected to.
- 8) ☐ Claim(s) \_\_\_\_\_ are subject to restriction and/or election requirement.

**Application Papers**

- 9) ☐ The specification is objected to by the Examiner.
- 10) ☐ The drawing(s) filed on \_\_\_\_\_ is/are: a) ☐ accepted or b) ☐ objected to by the Examiner.  
Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).  
Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).
- 11) ☐ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

**Priority under 35 U.S.C. § 119**

- 12) ☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).
- a) ☐ All b) ☐ Some \* c) ☐ None of:
1. ☐ Certified copies of the priority documents have been received.
  2. ☐ Certified copies of the priority documents have been received in Application No. \_\_\_\_\_.
  3. ☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

\* See the attached detailed Office action for a list of the certified copies not received.

**Attachment(s)**

- |   |   |
|---|---|
| 1) <input type="checkbox"/> Notice of References Cited (PTO-892)  | 4) <input type="checkbox"/> Interview Summary (PTO-413)<br>Paper No(s)/Mail Date. _____ |
| 2) <input type="checkbox"/> Notice of Draftsperson's Patent Drawing Review (PTO-948)  | 5) <input type="checkbox"/> Notice of Informal Patent Application                       |
| 3) <input checked="" type="checkbox"/> Information Disclosure Statement(s) (PTO/SB/08)<br>Paper No(s)/Mail Date <u>10/19/2006</u> . | 6) <input type="checkbox"/> Other: _____  |

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Applicant's amendments and remarks filed on 10/06/2006 are acknowledged. Claims 1 and 2 have been amended. New claims 3-19 have been added.

The objection of the Office Action mailed on 07/03/2006, has been withdrawn in response to the applicant's amendments. The amendment to specification has been entered. The rejection under 35 U.S.C. 112, 2<sup>nd</sup> paragraph has been overcome by the instant amendments.

The following is new rejection(s) necessitated by Applicant's amendment filed on 10/06/2006.

Claims 1-19 are currently pending in this application.

**35 U.S.C. 103(a) rejection**

1. The following is a quotation of 35 U.S.C. 103(a) which forms the basis for all obviousness rejections set forth in this Office action:

*(a) A patent may not be obtained though the invention is not identically disclosed or described as set forth in section 102 of this title, if the differences between the subject matter sought to be patented and the prior art are such that the subject matter as a whole would have been obvious at the time the invention was made to a person having ordinary skill in the art to which said subject matter pertains. Patentability shall not be negated by the manner in which the invention was made.*

**Claim 1 and newly added claims 3-17** are rejected under 35 U.S.C. 103(a) as being unpatentable over Lynch (U.S. Patent 4,471,001) of record.

Lynch teaches the hydrogenated maltose solution containing maltitol, sorbitol and minor amounts of higher saccharides and a process thereof, useful in formulating confections and food decorating specialities (abstract). Lynch discloses that aqueous maltitol syrups can contain 60-85% by weight solids (col.3, line 55). Lynch does not disclose specifically the water content in said aqueous maltitol solution, however Lynch

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discloses the solid content of 60-85% by weight in aqueous maltitol solution therefore one skilled in the art would assume the water content in the range of 15-40% by weight in the maltitol solution which renders the instantly claimed 32-38% water content obvious. Furthermore, Lynch discloses that maltitol syrup obtained from the hydrogenated maltose solution on a dry weight basis can have 25-94% maltitol, 2-30% sorbitol and 0.05-2% reducing sugars and higher saccharides on a dry weight basis (col.3, lines 55-59). It is noted that HP 3 and HP 4+ are defined as hydrogenated tri- and quat- and greater saccharides of reducing sugars (specification page 2, 3<sup>rd</sup> para.) therefore prior art's 25-94% maltitol, 2-30% sorbitol and 0.05-2% reducing sugars and higher saccharides on a dry weight basis render the maltitol solution of instant claim *prima facie* obvious.

With regard to the ranges of maltitol solution comprising 55-70%; and 62-70% by weight solids and 94.2 to 97% by weight maltitol claimed in the newly added claims 3-17, it would be within the scope of the artisan in this art to optimize them through routine experimentation in the absence of unexpected results with a particular combination.

Therefore, one of ordinary skill in the art would have found the applicants claimed maltitol solution; to have been obvious at the time the invention was made having the above cited reference before him. Since Lynch discloses the hydrogenated maltose solution containing maltitol, sorbitol and minor amounts of higher saccharides, one skilled in the art would have a reasonable expectation for success in following the teachings of Lynch to accomplish a maltitol solution of claim 1 by varying the amounts of solids to water contents and comprising each of maltitol, sorbitol, HP3 and HP4+ in a

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concentration to prevent maltitol from crystallizing out of solution. The motivation for doing so is provided by Lynch reference which discloses that "maltitol syrups are surprisingly resistant to the proliferation of airborne microorganisms such as mold when the total solids content is about 75% by weight and preferably about 80% (col. 1, lines 47-51) and the non-crystallizing maltitol solution is useful in cosmetic, pharmaceutical, confectionary and food preparations in the form of a clear transparent non-crystallizing gels (col.1, lines 60-65).

**Claim 2 and newly added claims 18-19** are rejected under 35 U.S.C. 103(a) as being unpatentable over Lynch (U.S. Patent 4,471,001) in view of Darsow (U.S. Patent 5,641,872) of record.

Lynch teaches the hydrogenation of maltose to produce a solution comprising maltitol and higher saccharides, useful in formulating confections and food decorating specialities (abstract). Lynch discloses the hydrogenation of aqueous corn syrup containing maltose, glucose and higher saccharides in the presence of nickel catalyst at 160° C at a pressure of hydrogen at 1500-2000 psi (col.2, lines 40-58). Lynch also discloses purification of said hydrogenated mixture through a cationic exchange and anionic exchange resin and thereafter concentration to remove water (col.2, lines 59-62). It is noted that HP 3 and HP 4+ are defined as hydrogenated tri- and quat- and greater saccharides of reducing sugars (specification page 2, 3<sup>rd</sup> para.) therefore prior art's hydrogenated mixture comprising maltitol, sorbitol and reducing sugars and higher

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saccharides on a dry weight basis (col.3, lines 55-59) render the maltitol solution obtained from the hydrogenation of maltose and glucose of instant claim obvious.

Lynch differs from the applicant's invention in that Lynch does not provide the use of a reaction promoter comprising magnesium powder in a hydrogenation reaction of maltose and glucose to produce a solution comprising maltitol.

Darsow teaches the use of non-catalytic pyrophoric metal powders such as aluminium, manganese or titanium in combination with the hydrogenation nickel catalyst in the hydrogenation reaction of maltose to produce epimer free maltitol (col.3, lines 50-65). Therefore one skilled in this art would be motivated to substitute the aluminium powder (pyrophoric metal powder) of said prior art with the non-catalytic pyrophoric metal powder of magnesium because the use of magnesium may also be helpful in the higher hydrogenation activity due to its reducing properties which renders the instantly claimed use of pyrophoric magnesium powder obvious. Darsow also discloses the use of the catalyst powder containing Ni/Mo/Al wherein the Al content is 6.1% (col.11, example 10).

With regard to the ion exchange step comprising a cation exchange and an ion exchange resin; subjecting the product of step (a) first to a cation exchange and then subsequently to an anion exchange resin or to a mixed cation and anion exchange resin claimed in the newly added claims 18 and 19 and amended claim 2, it would be within the scope of the artisan in this art to optimize them through routine experimentation in the absence of unexpected results with a particular combination.

Therefore, one of ordinary skill in the art would have found the applicants claimed method of making maltitol solution by subjecting a feedstock comprising maltose and glucose to a hydrogenation reaction in the presence of a hydrogenation catalyst and a reaction promoter comprising magnesium powder, to have been obvious at the time the invention was made having the above-cited references before him. Since Lynch teaches the hydrogenation of aqueous corn syrup containing maltose, glucose and higher saccharides in the presence of nickel catalyst and the use of an ion-exchange in the purification and Darsow overcomes the deficiency of Lynch reference by disclosing a the use of non-catalytic pyrophoric metal powders in combination with the hydrogenation nickel catalyst in the hydrogenation reaction of maltose to produce epimer free maltitol, one skilled in the art would have a reasonable expectation for success in combining both references to obtain a maltitol solution which is epimer free. Lynch provides the motivation to use the above-described process to prepare novel maltitol/sorbitol containing syrups useful in the manufacture of clear gels, which can be, used in cosmetic, pharmaceutical, confectionary and food preparations (col.3, lines 35-50).

**Rejection Maintained**

Rejection of claims 1-19 under 35 U.S.C. 103(a) is maintained for the reasons of record. Applicant's arguments traversing the rejection of claims 1-19 under 35 U.S.C. 103(a) have been fully considered but they are not persuasive.

### **Response to Arguments**

#### **Claims 1 and 3-17**

Applicant argues, "the Lynch reference clearly teaches away from maltitol syrups that contain less than 75% by weight solid content".

Lynch discloses that aqueous maltitol syrups can contain 60-85% by weight solids (col.3, line 55). Lynch does not disclose specifically the water content in said aqueous maltitol solution, however Lynch discloses the solid content of 60-85% by weight in aqueous maltitol solution. It may be possible that Lynch's compositions were estimated, however one skilled in the art would assume the water content in the range of 15-40% by weight in the maltitol solution which renders the instantly claimed 32-38% water content and 60-85% of weight solid content obvious.

Since Lynch discloses the hydrogenated maltose solution containing maltitol, sorbitol and minor amounts of higher saccharides, one skilled in the art would have a reasonable expectation for success in following the teachings of Lynch to accomplish a maltitol solution of claim 1 by varying the amounts of solids to water contents and comprising each of maltitol, sorbitol, hydrogenated trisaccharides and hydrogenated tetrasaccharides and hydrogenated polysaccharides higher than tetrasaccharides in a concentration to prevent maltitol from crystallizing out of solution. Lynch provides the motivation to use the above-described process to prepare novel maltitol/sorbitol



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containing syrups useful in the manufacture of clear gels, which can be, used in cosmetic, pharmaceutical, confectionary and food preparations (col.3, lines 35-50).

Claims 2, 18 and 19

Applicant argues, "since neither Lynch or Darsow contains any specific teaching concerning the use of a magnesium powder promoter in the hydrogenation process....".

Darsow teaches the use of non-catalytic pyrophoric metal powders such as aluminium, manganese or titanium in combination with the hydrogenation nickel catalyst in the hydrogenation reaction of maltose to produce epimer free maltitol (col.3, lines 50-65). One skilled in the art would have a reasonable expectation for success in following the teaching of Darsow to use magnesium powder promoter in the hydrogenation of the feedstock (a) of claims 2, 18 and 19 free of epimer.

2. Applicant's amendment necessitated the new ground(s) of rejection presented in this Office Action. Accordingly, **THIS ACTION IS MADE FINAL**. See MPEP § 706.07 (a). Applicant is reminded of the extension of time policy as set forth in 37 CFR 1.136(a). A shortened statutory period for reply to this final action is set to expire THREE MONTHS from the mailing date of this action. In the event a first reply is filed within TWO MONTHS of the mailing date of this final action and the advisory action is not mailed until after the end of the THREE-MONTH shortened statutory period, then the shortened statutory period will expire on the date the advisory action is mailed, and any extension fee pursuant to 37 CFR 1.136(a) will be calculated from the mailing date of the advisory action. In no event, however, will the statutory period for reply expire later than SIX MONTHS from the mailing date of this final action.


Any inquiry concerning this communication or earlier communications from the

Examiner should be directed to Devesh Khare whose telephone number is (571)272-0653. The examiner can normally be reached on Monday to Friday from 8:00 to 4:30.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Anna Jiang, Supervisory Patent Examiner, Art Unit 1623 can be reached at (571)272-0627. The official fax phone numbers for the organization where this application or proceeding is assigned is (571) 273-8300.

Information regarding the status of an application may be obtained from the Patent Application Information Retrieval (PAIR) system. Status information for published applications may be obtained from either Private PAIR or Public PAIR. Status information for unpublished applications is available through Private PAIR only. For more information about the PAIR system, see <http://pair-direct.uspto.gov>. Should you have questions on access to the Private PAIR system, contact the Electronic Business Center (EBC) at 866-217-9197 (toll-free).

Devesh Khare, Ph.D.,J.D.  
Art Unit 1623  
January 5, 2007

  
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